REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Attached hereto is a substitute specification as Exhibits A and B. Exhibit A is the substitute specification with markings to show all the changes relative to the immediate prior version. Exhibit B is a clean version of the substitute specification.

The herein amendments to the specification address informalities detailed in the Office Action, including the proper recitation of trademarks and labeling of sequences. No new matter has been added.

Claims 1-3, 5, 8, 9, and 28-36 are currently under consideration. Claims 2, 3, and 34 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 2 and 3 are amended as recommended in the Office Action. Claim 34 is clarified to recite "between 0.01 and 100mg of CMP per kg of body weight" rather than "between 0.01 and 100mg of active compound per kg of body weight." This is supported in the specification, for example, on page 17, lines 8-10.

No new matter has been added.

The Examiner is thanked for indicating that Applicant's IDS has been acknowledged.

The Examiner is respectfully requested to consider and make of record the article by Ozdemir et al. titled "Treatment with chitin microparticles is protective against lung histopathology in a murine asthma model" and published in Clin Exp Allergy 36: 960-968, 2006; the article by Leung et al. titled "Effect of anti-IgE therapy in patients with peanut allergy" and published in N Engl J Med 348: 986-993, 2003; the article by Barrody et al. titled "Antiallergic effects of H1-receptor antagonists" and published in Allergy 55(suppl. 64): 17-27, 2000; the article by Sampson titled "9. Food allergy" and published in J Allergy Clin Immunol 111(suppl. 2): S540-S547, 2003; and the article by Epstein titled "Are mouse models of allergic asthma useful for testing novel therapeutics?" and published in Exp Toxicol Pathol 57 (suppl. 2): 41-44, 2006. These references are cited on the accompanying Supplemental Information Disclosure Statement and PTO-1449.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicant is entitled.

II. CERTIFIED COPIES OF PRIORITY DOCUMENTS ARE SUBMITTED

The Office Action indicates that no certified copies of the priority documents have been provided. Submitted herewith is a certified copy Great Britain Patent Application No. 01200030.2 filed August 16, 2001 and Great Britain Patent Application No. 0206864.1 filed March 22, 2002. Accordingly, consideration of the certified copies of the priority documents is respectfully requested.

III. OBJECTIONS ARE OVERCOME

The Office Action alleges that trademarks presented in the specification should be capitalized and should include the generic terminology. In response, Applicant has amended the specification to capitalize all listed trademarks. Applicant has made an effort to identify the generic terminology of the trademarks, but have not been successful. Suggestions from the Examiner are welcomed for addressing this issue.

The Office Action also contends that a SEQ ID NO is not provided for a sequence disclosure of the specification (page 19, line 28) and thereby does not comply with 37 C.F.R. § 1.821 through § 1.826. In response, the specification has been amended to identify the sequence as SEQ ID NO 1. Further, a sequence listing in both written and computer readable form, as well as a statement confirming the content of the sequence listing information, are enclosed.

In addition, the Office Action asserts that claims 2 and 3 recite "group comprising...or" rather than "group consisting of...and." In response, Applicant has amended claims 2 and 3 as suggested in the Office Action.

Accordingly, reconsideration and withdrawal of the objections are respectfully requested.

IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, IS OVERCOME

Claim 34 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicant regards as the invention. Applicant respectfully traverses this rejection.

The Office Action contends that the phrase "active compound" is unclear, as it is uncertain whether the active compound refers to the chitin microparticles or allergen. In response, claim 34 has been amended to recite "between 0.01 and 100mg of CMP per kg of body weight."

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112 is respectfully requested.

V. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, IS OVERCOME

Claims 1, 5, 8, 9, and 28-36 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988),

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted]. *Id.* at 1404.

Determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), for example: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the

invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

Thus, it is respectfully submitted that for a proper Section 112, first paragraph, lack of enablement analysis, an Office Action must show that the *Wands* factors are not met. Simply, it is respectfully asserted that the lack of enablement rejection fails to provide a fact based analysis using the *Wands* factors that supports the proposition the claimed invention require **undue** experimentation.

The Office Action asserts that the specification "does not reasonably provide enablement for a method of treating allergy to any allergen or allergy treatable by IgE and by allergic desensitization." According to the Office Action, the specification fails to provide sufficient guidance with respect to treating allergy by chitin microparticles intranasally other than allergy caused by house dust mite and fungal spores, Dermatophagoides pteronyssinus and Aspergillus fumigatus, respectively. The Office Action refers to Merck Manual of Diagnosis and Therapy as allegedly suggesting different methods of treatment for specific allergens and that there is no universal allergy treatment effective to any allergens.

In response, Applicant argues that the specification is enabling for a method of treating allergies as disclosed in claim 1. The state of the art indicates that chitin microparticles (CMP) can be used to treat allergies other than aeroallergens and that the scope of the claims is supported. For instance, Ozdemir et al. (Clin Exp Allergy 36: 960-968, 2006) mentions that intransasal administration of CMP can have a beneficial effect in preventing and treating asthma. Moreover, Leung et al. (N Engl J Med 348: 986-993, 2003), which refers to the efficacy of anti-IgE therapies to diminish the sensitivity to food allergies, would indicate to a person skilled in the art that methods to reduce serum IgE can be effective in treating food allergies. Thus, the state of the art provides evidence that the scope of the claims is not unreasonable and that a skilled artisan could perform the instant invention without undue experimentation.

The Office Action, in order to support its argument that there is no universal treatment for allergies, uses antihistamines as an example of a widely recognized treatment for allergies that cannot treat all allergies, namely food allergies. Applicant respectfully responds that the example of antihistamines in fact does not provide any further support to the Office Action's contention. As mentioned in the Merck Manual of Diagnosis and Therapy and in Baroody et al.

(Allergy 55 suppl. 64: 17-27, 2000), antihistamines act by competitively binding to histamine cellular receptors (H1 receptors) that are located on nerve endings, smooth muscles, and glandular cells. Furthermore, Sampson (J Allergy Clin Immunol 111 suppl. 2: S540-S547, 2003) mentions that antihistamines can only partially relieve some food allergy symptoms but do not block systemic reactions. Clearly, since antihistamines can only treat symptoms, they will not provide relief to food allergies if the food allergy symptoms are not targeted. Therefore, one skilled in the art would not expect antihistamines to act as a universal allergy treatment effective against any allergens.

Importantly, antihistamine treatments and the CMP method of the present invention act through different pathways. While antihistamines only treat symptoms, the present invention has been shown in the specification to have Th1 immunostimulatory properties, which can be applicable to a variety of allergies that include aeroallergies, asthma, and food allergies. Thus, a skilled artisan would not compare antihistamines and their inability to perform as a universal allergy treatment to the CMP method disclosed in the instant claims.

In addition, the Office Action further asserts that the specification does not provide enablement for "a method of treating allergy by administering chitin microparticles in humans or in horses." The Office Action contends that the Applicant "fails to provide any in vivo working example for treating any allergies other than allergy to aeroallergens by administering chitin microparticles in humans or in horses."

In response, the Examiner is respectfully reminded that a specification need not contain any example of the invention, as the issue is whether the disclosure enables one skilled in the art to practice the invention without undue experimentation. *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). Simply, a determination that undue experimentation is necessary to practice the invention does not necessarily follow from a lack of examples in the specification. And, the Examiner is further respectfully reminded that an applicant need not describe all actual embodiments of a claimed invention.

Moreover, the state of the art provides that mice are used as an accepted model for investigating allergies and that the results can be applicable to human. For example, in examining allergic asthma, Epstein et al. (Exp Toxicol Pathol. 57 suppl 2:41-4, 2006) mentions that "experimental mouse allergic asthma is a reliable, clinically relevant facsimile of human disease" (abstract). This indicates that the results acquired from a mouse model can be used to

predict the results in human. Notably, the specification offers substantial examples and guidance for performing the instant invention in mice. Thus, the Office Action does not provide evidence that the instant invention would require undue experimentation due to the working examples, direction provided in the specification, the unpredictability in the art, or the amount of experimentation required enabling a skilled artisan to practice the invention.

VI. REJECTION UNDER 35 U.S.C. § 103(a) IS OVERCOME

Claims 1-3, 5, 8, and 28-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata et al. (J Immunol 164: 1314-21, 2000; hereinafter "Shibata") in view of Clinical Report (Pediatrics 100: 143-152, 1997). Applicant respectfully traverses this rejection.

According to the Office Action, Shibata refers to a method of treating an allergy by aeroallergen by orally administering chitin microparticles in saline, while Clinical Report mentions that nasal/intranasal administration is a well recognized route of administration for delivering drugs in allergy treatment.

In response, Applicant respectfully notes that Section 2143 of the MPEP states that, in order to establish a case of obviousness, there must be a reasonable expectation of success. As such, the instant claims are not obvious in light of Shibata and the Clinical Report, because one skilled in the art would not presume that the combination of these references would be successful. As noted in the Clinical Report, there are numerous considerations that have to be addressed when developing a method to administer a product intranasally or by inhalation. For instance, in determining the amount of the product absorbed via intranasal or inhalation administration, one skilled in the art would have to consider the product concentration, vehicle of product delivery, mucosal contact time, venous drainage of muscosal tissues, and the size of the product (Clinical Reports, page 5). Distrbution of the product is dependent upon, for example, the formulation, dilution, and particle size (Clinical Reports, page 6). Furthermore, the skilled artisan would also have to be concerned about the product metabolism in the respiratory tract and reduction of a systemic effect, mucociliary transport causing increased or decreased product residence time, and local toxic effects of the product (Clinical Reports, page 6). Therefore, it is not a menial task to develop an intranasal- or inhalation-form of a product from an oral-form of the product. Hence, it could not be expected that an intranasal- or inhalation-form of CMP could be successfully developed.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-3, 5, 8, and 28-36 under 35 U.S.C. 103(a) are respectfully requested.

REQUEST FOR INTERVIEW

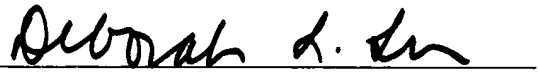
If any issue remains as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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